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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,870	03/07/2001	Mary H. Romans	NERV-00100	5447

7590 12/02/2002

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EXAMINER
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BERTOGLIO, VALERIE E

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/800,870

Applicant(s)

ROMANS, MARY H.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9, 12-17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Election/Restriction*.

### **DETAILED ACTION**

Claims 10 and 11 will not be considered because they are wholly unclear. It is not clear what the "product" in claim 10 refers to. Therefore, the structure of the product in claim 10 cannot be determined. Furthermore, a cell assay (claim 11) is not a product, making claim 11 even more unclear.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4 and 6-9, drawn to a method for producing non-destructive nerve alterations in an animal, classified in class 800, subclass 8.
- II. Claim 5, drawn to an animal model wherein compression is placed around a nerve non-surgically, classified in class 800, subclass 8.
- III. Claims 12-15, drawn to a method of screening treatments using a model of pain, classified in various classes and subclasses.
- IV. Claims 16-17, drawn to a composition for treatment of pain, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because, the methods of Group I do not require the animal model of Group II. The search required for the methods of making non-destructive nerve alterations and the animal model wherein compression is placed around a nerve are divergent. The scope of placing compression on a nerve non-surgically (claim 5) is different in scope than the methods of claims 1-4 and 6-9. The burden required to search Groups I and II together would be undue.

Inventions I and III are patentably distinct because, the methods of Group I can be used to generate an animal model while the methods of Group III can be used to screen for treatments of chronic pain. The protocols and reagents required for each group are independent, materially distinct and separate. The burden required to search Groups I and III together would be undue.

Inventions I and IV are patentably distinct because, the methods of Group I can be used to generate an animal model while the composition of Group IV can be used to treat of chronic pain. The method is not necessary for the composition and the composition is not necessary for the method. The burden required to search Groups I and IV together would be undue.

Inventions II and III are patentably distinct because, the animal model of Group II can be used to study chronic pain while the methods of Group III can be used to screen for treatments for chronic pain. The protocols and reagents required for the animal model and the methods are materially distinct and separate. The animal model is not necessary for the methods and the methods are not necessary for the animal model. The burden required to search Groups II and III together would be undue.

Inventions II and IV are patentably distinct because, the animal model of Group II can be used to study chronic pain while the composition of Group IV can be used to treat chronic pain. The protocols and reagents required for the animal and the treatment are materially distinct and separate. The animal model is not necessary for the treatment and the treatment is not necessary for the animal model. The burden required to search Groups II and IV together would be undue.

Inventions III and IV are patentably distinct because, the methods of Group III can be used to identify treatments of chronic pain while the composition of Group IV can be used to treat chronic pain. The protocols and reagents required for the methods and the composition are materially distinct and separate. The methods of Group III are not necessary to treat chronic pain nor are compositions for treating chronic pain necessary to screen for treatments. The burden required to search Groups III and IV together would be undue.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches for the groups are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Valarie Bertoglio  
Patent Examiner



MICHAEL C. WILSON  
PATENT EXAMINER